with concerted use of incentives, leverage and pressure with all the parties, should maintain the sense of urgency necessary to move steadily toward an enduring peace. While the benchmark process will be useful as a tool both to promote and review the pace of Dayton implementation, the estimated target dates established will be notional, and their attainment dependent upon a complex set of interdependent factors.

We will provide a supplemental report once NATO has agreed upon detailed criteria and estimated target dates. The continuing 6-month reviews of the status of implementation will provide a useful opportunity to continue to consult with Congress. These reviews, and any updates to the estimated timelines for implementation, will be provided in subsequent reports submitted pursuant to Public Law 105–174. I look forward to continuing to work with the Congress in pursuing U.S. foreign policy goals in Bosnia and Herzegovina.

WILLIAM J. CLINTON.

THE WHITE HOUSE, *July 28, 1998.*

By unanimous consent, the message was referred to the Committee on International Relations and ordered to be printed (H. Doc. 105–292).

### ¶77.43 DEPARTMENT OF TRANSPORTATION APPROPRIATIONS FOR FY 1999

The SPEAKER pro tempore, Mr. LAHOOD, pursuant to House Resolution 510 and rule XXIII, declared the House resolved into the Committee of the Whole House on the state of the Union for the consideration of the bill (H.R. 4328) making appropriations for the Department of Transportation and related agencies for the fiscal year ending September 30, 1999, and for other purposes.

The SPEAKER pro tempore, Mr. LAHOOD, by unanimous consent, designated Mr. GILLMOR as Chairman of the Committee of the Whole; and after some time spent therein,

## THURSDAY, JULY 30 (LEGISLATIVE DAY OF JULY 29), 1998

The SPEAKER pro tempore, Mr. LAHOOD, assumed the Chair.

When Mr. GILLMOR, Chairman, pursuant to House Resolution 510, reported the bill, as amended by that rule, back to the House with further sundry amendments adopted by the Committee.

The previous question having been ordered by said resolution.

Pursuant to House Resolution 510, the following amendments in House Report 105–651 were considered as adopted:

Page 57, strike sections 345 and 346.

At the end of title III (preceding the short title; page—, after line—), add the following:

**SEC.-. CONVEYANCE OF COAST GUARD PROPERTY TO JACKSONVILLE UNIVERSITY IN JACKSON-VILLE, FLORIDA.**

(a) AUTHORITY TO CONVEY.—

(1) IN GENERAL.—The Secretary of Transportation may convey to Jacksonville University, located in Jackson, Florida, without consideration, all right, title, and interest of the United States in and to the property comprising the Long Branch Rear Range Light, Jacksonville, Florida.**4(2)** IDENTIFICATION OF PROPERTY.—The Secretary may identify, describe, and determine the property to be conveyed under this section.

(b) TERMS AND CONDITIONS.—Any conveyance of any property under this section shall be made—

(1) subject to such terms and conditions as the Commandant may consider appropriate; and

(2) subject to the condition that all right, title, and interest in and to the property conveyed shall immediately revert to the United States if the property, or any part thereof, ceases to be used by Jacksonville University.

The following further amendments, reported from the Committee of the Whole House on the state of the Union, were agreed to:

On page 11, line 19 of the bill, after ''5,532,558,000,'', insert the following: ''of which $1,972,500,000 shall be derived from the Airport and Airway Trust Fund''.

On page 26, strike lines 1 through 2.

At the end of the bill, insert after the last section (preceding the short title) the following new section:

SEC. . None of the funds made available in title I under the heading ''OFFICE OF THE SECRETARY—AMTRAK REFORM COUNCIL'' may be used for payments to outside consultants.

At the end of title III, insert the following:

None of the funds made available in this Act may be used for improvements to the Miller Highway in New York City, except for funds resulting from obligations pursuant to sections 1601 and 1602 of the Transportation Equity Act for the 21st Century (P.L. 105–178).

Page 53, line 15, strike ''is hereby authorized to'' and insert ''shall''.

Page 53, line 18, strike the colon and all that follows through ''time as'' on line 20 and insert ''if''.

The bill, as amended, was ordered to be engrossed and read a third time, was read a third time by title.

The question being put,

Will the House pass said bill?

The SPEAKER pro tempore, Mr. LAHOOD, announced that pursuant to clause 7 of rule XV the yeas and nays were ordered, and the call was taken by electronic device.

It was decided in the affirmative ..... { Yeas ..... 391 / Nays ..... 25

### ¶77.44 [Roll No. 355]

YEAS—391

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Abercrombie | Bereuter | Brown (CA) | Clyburn | Hoyer | Oberstar |
| Ackerman | Berman | Brown (FL) | Coble | Hulshof | Obey |
| Aderholt | Berry | Brown (OH) | Coburn | Hunter | Olver |
| Allen | Bilbray | Bryant | Collins | Hutchinson | Ortiz |
| Andrews | Bilirakis | Bunning | Combest | Hyde | Owens |
| Archer | Bishop | Burton | Condit | Inglis | Oxley |
| Armey | Blagojevich | Buyer | Conyers | Istook | Packard |
| Bachus | Bliley | Callahan | Cook | Jackson (IL) | Pallone |
| Baesler | Blumenauer | Calvert | Cooksey | Jackson-Lee (TX) | Pappas |
| Baker | Blunt | Camp | Costello | Jefferson | Parker |
| Baldacci | Boehlert | Canady | Coyne | Jenkins | Pascrell |
| Ballenger | Boehner | Cannon | Cramer | John | Pastor |
| Barcia | Bonilla | Capps | Crapo | Johnson (CT) | Paxon |
| Barr | Bonior | Cardin | Cubin | Johnson (WI) | Payne |
| Barrett (NE) | Bono | Carson | Cummings | Johnson, E. B. | Pease |
| Barrett (WI) | Borski | Castle | Cunningham | Kanjorski | Pelosi |
| Bartlett | Boswell | Chambliss | Danner | Kaptur | Peterson (MN) |
| Barton | Boucher | Christensen | Davis (FL) | Kelly | Peterson (PA) |
| Bass | Boyd | Clay | Davis (IL) | Kennedy (MA) | Petri |
| Bateman | Brady (PA) | Clayton | Davis (VA) | Kennedy (RI) | Pickering |
| Bentsen | Brady (TX) | Clement | Deal | Kennelly | Pickett |
| | | | DeFazio | Kildee | Pitts |
| | | | DeGette | Kilpatrick | Pombo |
| | | | Delahunt | Kim | Pomeroy |
| | | | DeLauro | Kind (WI) | Porter |
| | | | DeLay | King (NY) | Portman |
| | | | Deutsch | Kingston | Poshard |
| | | | Diaz-Balart | Kleczka | Price (NC) |
| | | | Dickey | Klink | Pryce (OH) |
| | | | Dicks | Klug | Quinn |
| | | | Dixon | Knollenberg | Radanovich |
| | | | Doggett | Kolbe | Rahall |
| | | | Dooley | LaFalce | Ramstad |
| | | | Doolittle | LaHood | Rangel |
| | | | Doyle | Lampson | Redmond |
| | | | Dreier | Lantos | Regula |
| | | | Duncan | Largent | Reyes |
| | | | Dunn | Latham | Riggs |
| | | | Edwards | Lazio | Riley |
| | | | Ehlers | Leach | Rivers |
| | | | Ehrlich | Lee | Rodriguez |
| | | | Emerson | Levin | Roemer |
| | | | Engel | Lewis (CA) | Rogan |
| | | | English | Lewis (GA) | Rogers |
| | | | Ensign | Lewis (KY) | Rohrabacher |
| | | | Eshoo | Linder | Ros-Lehtinen |
| | | | Etheridge | Lipinski | Rothman |
| | | | Evans | Livingston | Roukema |
| | | | Everett | LoBiondo | Roybal-Allard |
| | | | Farr | Lofgren | Rush |
| | | | Fattah | Lowey | Ryun |
| | | | Fawell | Lucas | Sabo |
| | | | Filner | Luther | Sanchez |
| | | | Foley | Maloney (CT) | Sanders |
| | | | Forbes | Maloney (NY) | Sandlin |
| | | | Ford | Manton | Sawyer |
| | | | Fossella | Manzullo | Saxton |
| | | | Fowler | Markey | Scarborough |
| | | | Fox | Martinez | Schaefer, Dan |
| | | | Franks (NJ) | Mascara | Schumer |
| | | | Frelinghuysen | Matsui | Scott |
| | | | Frost | McCarthy (MO) | Sensenbrenner |
| | | | Furse | McCarthy (NY) | Serrano |
| | | | Gallegly | McCollum | Shaw |
| | | | Ganske | McCrery | Shays |
| | | | Gejdenson | McDermott | Sherman |
| | | | Gekas | McGovern | Shimkus |
| | | | Gephardt | McHale | Shuster |
| | | | Gibbons | McHugh | Sisisky |
| | | | Gilchrest | McInnis | Skaggs |
| | | | Gillmor | McIntosh | Skeen |
| | | | Gilman | McIntyre | Skelton |
| | | | Goode | McKeon | Slaughter |
| | | | Goodlatte | McKinney | Smith (MI) |
| | | | Goodling | McNulty | Smith (NJ) |
| | | | Gordon | Meehan | Smith (TX) |
| | | | Goss | Meek (FL) | Smith, Adam |
| | | | Granger | Meeks (NY) | Smith, Linda |
| | | | Green | Menendez | Snowbarger |
| | | | Greenwood | Metcalf | Snyder |
| | | | Gutierrez | Mica | Solomon |
| | | | Gutknecht | Millender-McDonald | Spence |
| | | | Hall (TX) | Miller (CA) | Spratt |
| | | | Hamilton | Miller (FL) | Stabenow |
| | | | Hansen | Minge | Stenholm |
| | | | Hastert | Mink | Stokes |
| | | | Hastings (FL) | Mollohan | Strickland |
| | | | Hastings (WA) | Moran (VA) | Stupak |
| | | | Hefley | Morella | Sununu |
| | | | Hefner | Myrick | Talent |
| | | | Hilleary | Nadler | Tanner |
| | | | Hilliard | Neal | Tauscher |
| | | | Hinchey | Nethercutt | Tauzin |
| | | | Hinojosa | Neumann | Taylor (MS) |
| | | | Hobson | Ney | Taylor (NC) |
| | | | Holden | Northup | Thomas |
| | | | Hooley | Norwood | Thompson |
| | | | Horn | Nussle | Thornberry |
| | | | Hostettler | | Thune |
| | | | Houghton | | Thurman |

| | | |
|---|---|---|
| Tiahrt | Walsh | Weygand |
| Tierney | Wamp | White |
| Torres | Waters | Whitfield |
| Towns | Watkins | Wicker |
| Traficant | Watt (NC) | Wilson |
| Turner | Watts (OK) | Wise |
| Upton | Waxman | Wolf |
| Velazquez | Weldon (FL) | Woolsey |
| Vento | Weldon (PA) | Wynn |
| Visclosky | Weller | Young (AK) |

NAYS—25

| | | |
|---|---|---|
| Burr | Hoekstra | Schaffer, Bob |
| Campbell | Jones | Sessions |
| Chabot | Kasich | Shadegg |
| Chenoweth | Kucinich | Souder |
| Crane | Moran (KS) | Stearns |
| Graham | Paul | Stump |
| Hayworth | Royce | Wexler |
| Herger | Salmon | |
| Hill | Sanford | |

NOT VOTING—18

| | | |
|---|---|---|
| Becerra | Gonzalez | Moakley |
| Cox | Hall (OH) | Murtha |
| Dingell | Harman | Smith (OR) |
| Ewing | Johnson, Sam | Stark |
| Fazio | LaTourette | Yates |
| Frank (MA) | McDade | Young (FL) |

So the bill was passed.

A motion to reconsider the vote whereby said bill was passed was, by unanimous consent, laid on the table.

*Ordered,* That the Clerk request the concurrence of the Senate in said bill.

## ¶77.45 PRODUCT LIABILITY

On motion of Mr. GEKAS, by unanimous consent, the Committee of the Whole House on the state of the Union was discharged from further consideration of the bill (H.R. 872) to establish rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers, and for other purposes.

When said bill was considered and read twice.

The following amendment, recommended by the Committee on the Judiciary, was then agreed to:

Strike out all after the enacting clause, and insert the following:

**SECTION 1. SHORT TITLE**

This Act may be cited as the ''Biomaterials Access Assurance Act of 1998''.

**SEC. 2. FINDINGS.**

The Congress finds that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; or

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce;

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for life-saving medical devices is one such circumstance; and

(17) the protections set forth in this Act are needed to assure the continued supply of materials for life-saving medical devices, although such protections do not protect negligent suppliers.

**SEC. 3. DEFINITIONS.**

As used in this Act:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf of or through the estate of a deceased individual into whose body, or in contact with whose blood or tissue the implant was placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.—Such term does not include—

(i) a provider of professional health care services in any case in which—

(I) the sale or use of an implant is incidental to such services; and

(II) the essence of the professional health care services provided is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this Act may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding, and

(bb) except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—Such term includes a manufactured piece of an implant that—

(i) has significant non-implant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—